IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

PAMELA A. AHMED,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Civil Action No. 1:22-00190-KD-N**
	)	
JOHNSON & JOHNSON HEALTHCARE SYSTEMS, INC. and MEDICAL DEVICE BUSINESS SERVICES, INC.,	)	
	)	
Defendants.	)	

ORDER

This matter is before the Court on Defendants Johnson & Johnson Healthcare Systems, Inc. and Medical Device Business Services, Inc's (collectively "Defendants") Motion to Exclude Opinions of Richard Edwards, (Doc. 51), and Memorandum in Support thereof, (Doc. 52), Motion to Exclude Opinions of Dr. Kenneth Sands, (Doc. 53), and Memorandum in Support thereof, (Doc. 54), Plaintiff Pamela Ahmed's ("Plaintiff" or Ms. "Ahmed") Responses In Opposition, (Docs. 61-62), and Defendants' Replies, (Docs. 65-66). Upon consideration for the reasons set forth herein, Defendants' Motion to Exclude Opinions of Richard Edwards, (Doc. 51), is **GRANTED** to the extent that Mr. Edwards is prohibited from testifying as to any alternative design for the Hip Implant but is **DENIED** as to every other respect. Defendants' Motion to Exclude Opinions of Dr. Kenneth Sands, (Doc. 53), is **DENIED**.

This matter is also before the Court on Defendants' Motion for Summary Judgment, (Doc. 55), and Memorandum in Support thereof, (Doc. 56), Plaintiff's Response in Opposition, (Doc. 60), and Defendants' Reply, (Doc. 67). Upon consideration and for the reasons set forth herein, Defendants' Motion for Summary Judgment, (Doc. 55), is **GRANTED** as to Plaintiff's Count One

(Product Liability/AEMLD), Count Two (Fraud/Suppression), Count Three (Failure to Warn and Defect), Count Four (Breach of Express Warranty), Count Six (Negligence), and Count Seven (Third-Party Beneficiary), but is **DENIED** as to Plaintiff's Count Five (Breach of Implied Warranty).[1]

I. BACKGROUND

Ms. Pamela Ahmed underwent a right total hip arthroplasty on November 4, 2020, during which Dr. Todd Engerson implanted her with a prosthetic hip replacement device (the "Hip Implant"). (Doc. 56 at 7; Doc. 60 at 1). The Hip Implant consisted of a Pinnacle Altrx polyethylene liner, Pinnacle cup, and Biolix ceramic femoral head. (Doc. 56 at 7; Doc. 60 at 1-2; Doc. 63-1 at 3-4). Defendants manufactured and distributed these components. (Doc. 60 at 1; Doc. 63-1 at 3-4). Ms. Ahmed began physical therapy in November 2020. (Doc. 56-5 at 4). On or about December 25, some six weeks after surgery, Ms. Ahmed, while getting up to walk, heard a "popping" sound come from her right hip that "sounded like a firecracker go off." (Doc. 63-2 at 7). Three days later, she visited an orthopedist, and on January 25, 2021, "she told her doctor that the hip pops and locks up sometimes." (Doc. 56-5 at 4). Ms. Ahmed fell just prior to February 24, 2021. (Id.). During a visit with Dr. Engerson the next day, "radiographs revealed the hip was eccentrically

[1] The Complaint names as parties "FICTITIOUS PARTIES A, B, C, and/or D" – "the persons, firms, entities, or corporations responsible or involved in the design, manufacture or distribution/selling of the product(s) that injured Plaintiff during the course of her treatment for the hip replacement made the basis of this Complaint." (Doc. 1-2 at 3). "As a general matter, fictitious-party pleading is not permitted in federal court." Richardson v. Johnson, 598 F.3d 734, 738 (11th Cir. 2010). However, when a case is removed from the Alabama state court system, as here – where fictitious party pleading, subject to certain limitations, is permissible, see Ala. R. Civ. P. 9(h) – "an absolute rule against its use in federal court actions seems unwise and might violate the federal court's obligation to apply the rules of decision of the forum state." Gaines v. Choctaw Cnty. Comm'n, 242 F. Supp. 2d 1153, 1166 (S.D. Ala. 2003) (internal citation omitted). Nonetheless, the deadline in this case for any motion to amend the pleadings under Rule 15(a)(2) or to join other parties was April 7, 2023. (Doc. 20 at 5-6). Plaintiff has failed to move to amend the Complaint to substitute real parties for "Fictitious Parties A, B, C, and/or D" at all, much less within the timeline set out in the Rule 16(b) Scheduling Order. The Court thus *sua sponte* dismisses "FICTITIOUS PARTIES A, B, C, and/or D" as parties. See Fed. R. Civ. P. 21 ("On motion or on its own, the court may at any time, on just terms, add or drop a party."); Cook v. Corizon, LLC, No. 2:17-CV-178, 2019 WL 2076392, at *6 (M.D. Ala. May 10, 2019) (dismissing *sua sponte* fictitious defendants).

located," (Doc. 56-4 at 4), and Dr. Engerson noted that she needed a "right hip poly exchange," (Doc. 56-5 at 4). Ms. Ahmed underwent revision hip arthroplasty on March 1, 2021. (Doc. 56-4 at 4). While she tolerated the revision surgery, she underwent more surgery for acute infection that March, (Doc. 56-6 at 5), which was concentrated in the right hip, (Doc. 63-3 at 8-9). She experienced two subsequent dislocations of the right hip. (Doc. 56-4 at 4-5; Doc. 56-5 at 4).

On April 12, 2022, Ms. Ahmed sued Defendants in Mobile County Circuit Court. (See Doc. 1-2). She puts forward seven claims: "product liability/AEMLD, fraud/suppression, failure to warn and defect, breach of express warranty, breach of implied warranty, negligence, and third-party beneficiary." (Id. at 5-9). Ms. Ahmed prays for five categories of damages: "pain and suffering, mental anguish, medical extreme, physical disability, and anxiety." (Id. at 10). On May 11, 2022, Defendants removed this action to the United States District Court for the Southern District of Alabama. (Doc. 1). Defendants have since moved to exclude all opinions of Plaintiff's expert, Mr. Richard Edwards, and Plaintiff's rebuttal expert, Dr. Kenneth Sands. (Docs. 51-54). Defendants also moved for summary judgment. (Docs. 55-56).

II. LEGAL STANDARD

A. Admissibility of Expert Testimony

Federal Rule of Evidence 702, as explained by the Supreme Court in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), and its progeny, govern the admissibility of expert testimony. City of Tuscaloosa v. Harcos Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702.

District courts "must act as 'gatekeepers' to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" Knepfle v. J-Tech Corp., 48 F.4th 1282, 1293 (11th Cir. 2022) (quoting Daubert, 509 U.S. at 589). The Eleventh Circuit interprets Rule 702 and Daubert such that expert testimony may be admitted into evidence if:

> (1) The expert is qualified to testify competently regarding the matters he intends to address;
>
> (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and
>
> (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

City of Tuscaloosa, 158 F.3d at 562. "[A]lthough there is some overlap among the inquiries into an expert's qualifications, the reliability of his proffered opinion and the helpfulness of that opinion, these are distinct concepts that courts and litigants must take care not to conflate." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003). The trial judge's gatekeeping obligation under Daubert is not limited to scientific testimony but extends to other kinds of expert testimony based on technical or specialized knowledge. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147-49 (1999).

The Eleventh Circuit has explained that this gatekeeping function is especially important because no other witness is free to opine on matters without firsthand knowledge of the facts in the case or rely upon otherwise inadmissible hearsay so long as the facts or data are of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject. U.S. v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004); see Fed. R. Evid. 703. That said, "courts must remain chary not to improperly use the admissibility criteria to supplant a plaintiff's right to a jury trial." Moore v. Intuitive Surgical, Inc., 995 F.3d 839, 850 (11th Cir. 2021) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.") (quoting Daubert, 509 U.S. at 596). Additionally, courts must abstain from credibility determinations and any assessment of the merits of the expert witness's opinion, matters reserved exclusively to juries, and instead focus on whether the witness satisfies the requirements under Rule 702 and Daubert. Jones v. Lowe's Home Ctrs., LLC, No. 6:17-CV-2018, 2019 WL 1254814, at *2 (M.D. Fla. Mar. 19, 2019); Quiet Tech., 326 F.3d at 1341 ("[I]t is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence.").

Effective December 1, 2023, Rule 702 clarifies that the proponent of expert testimony must meet all the requirements for admissibility by a preponderance of the evidence. Fed. R. Evid. 702 Advisory Comm.'s Note to 2023 Amend.[2] However, once the court finds it more

[2] The Eleventh Circuit has held since 1999 that the burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, who must prove admissibility by a preponderance of the evidence. Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999) (citing Daubert, 509 U.S. at 592 n.10). As such, this amendment to Rule 702 should have little effect on post-1999 Eleventh Circuit precedent concerning Rule 702.

likely than not that the admissibility requirement is met, attacks by the opponent will go only to the weight of the evidence. Id.

B. Summary Judgment

District courts shall grant summary judgment when the movant shows that there is no genuine dispute as to any material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the initial responsibility of informing the district court of the basis for its motion, and "identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," which it believes demonstrate the absence of a genuine issue of material fact. U.S. v. Four Parcels of Real Prop. in Greene and Tuscaloosa Cntys. in State of Ala., 941 F.2d 1428, 1437 (11th Cir. 1991); see Fed. R. Civ. P. 56(c). To discharge this "initial responsibility" when the nonmoving party has the burden of proof at trial, the moving party is not required to support its motion with such material negating the opponent's claim. Four Parcels, 941 F.2d at 1437-38. Rather, the movant may "show – that is, point out to the district court – that there is an absence of evidence to support the non-moving party's case." Id. at 1438 (alteration adopted); see Fed. R. Civ. P. 56(c)(1)(B) ("A party asserting that a fact cannot be . . . genuinely disputed must support the assertion by: showing that . . . an adverse party cannot produce admissible evidence to support the fact."). Alternatively, the movant may support its motion with affirmative evidence demonstrating the nonmovant's inability to prove its case at trial. Four Parcels, 941 F.2d at 1438. If the moving party succeeds in showing "the absence of a triable issue of fact by either method, the burden on summary judgment shifts to the non-moving party, who must show that a genuine issue remains for trial." Id. The non-moving party must go beyond the pleadings and present affirmative evidence that indicates that a genuine issue of material fact exists. Porter v. Ray, 461 F.3d 1315, 1320 (11th Cir. 2006). "If the

nonmoving party fails to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof," the movant is entitled to summary judgment. Four Parcels, 941 F.2d at 1438. "In reviewing whether the nonmoving party has met its burden, the court must stop short of weighing the evidence and making credibility determinations of the truth of the matter." Tipton v. Bergrohr GMBH-Siegen, 965 F.2d 994, 998-99 (11th Cir. 1992). Rather, the non-movant's evidence is to be believed, with all justifiable inferences drawn in her favor. Id. at 999.

A dispute is "genuine," such that summary judgment is improper, "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The substantive law identifies which facts are material. Id. Finally, after giving notice and a reasonable time to respond, the Court may grant the summary judgment motion on grounds not raised by a party. Fed. R. Civ. P. 56(f)(2).

III. ANALYSIS OF MOTION TO EXCLUDE OPINIONS OF RICHARD EDWARDS

A. Mr. Edwards Is Qualified to Testify as an Expert Regarding the Hip Implant

Experts may be qualified in various ways, from scientific training or education to field experience. Frazier, 387 F.3d at 1260-61; Fed. R. Evid. 702 ("A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify . . . .") (emphasis added). Assessing whether the expert is qualified is a less thorough inquiry than analyzing the reliability of his proposed testimony. Knepfle, 48 F.4th at 1294; Hendrix v. Evenflo Co., Inc., 255 F.R.D. 568, 585 (N.D. Fla. 2009) ("[T]he standard for determining an expert's qualifications to testify on a given topic is not stringent. So long as the witness is minimally qualified, objections to the level of the expert's expertise go to credibility and weight, not admissibility.") (internal quotations and citation omitted and alteration adopted); Thomas v. Evenflo Co., Inc., No. 2:02-CV-2001, 2005

WL 6133409, at *6 (N.D. Ala. Aug. 11, 2005) ("The Court's own review has discovered that, generally, the standard for qualifying expert witnesses is liberal."). As a preliminary matter, conflating qualifications to testify with reliability constitutes an abuse of discretion. Moore, 995 F.3d at 852-53 ("This distinction is not academic. Qualifications and reliability remain separate prongs of the Daubert inquiry that answer two separate questions."); Quiet Tech., 326 F.3d at 1341-42 ("Viewed more abstractly, if methodological unreliability or a lack of intellectual rigor precluded a witness from being qualified as an expert, then this would largely eviscerate the reliability determination, as one's expert qualification foreordain the conclusion that the methods employed by that individual were reliable. Yet our caselaw plainly establishes that one may be considered an expert but still offer unreliable testimony.").

An expert is qualified to offer his opinion on a subject if the subject matter of his testimony is "sufficiently within his expertise" even when the expert does not have experience regarding the narrow issue at hand. Maiz v. Virani, 253 F.3d 641, 665 (11th Cir. 2001) (holding that the defendants' insistence that the expert had no real estate development experience went more to the foundation for his testimony than his qualifications to calculate the plaintiffs' damages when the expert had a "Ph.D. in economics from Yale, extensive experience as a professional economist, and a substantial background in estimating damages"); see also McDowell v. Brown, 392 F.3d 1283, 1297 (11th Cir. 2004) ("The proffered physician need not be a specialist in the particular medical discipline to render expert testimony relating to that discipline.").

The Eleventh Circuit has made clear that its Rule 702 case law "does not support a bright line rule that an expert witness is qualified to testify regarding the cause of an injury only if he personally has used the defective product." Moore, 995 F.3d at 854 ("Instead, this Court has explicitly disclaimed such a rule."). Precluding a board-certified OB/GYN who had practiced for

over forty years, performed over four thousand hysterectomies, and was a professor of obstetrics and gynecology from testifying regarding a robotically assisted hysterectomy procedure merely because he did not use robotic tools was thus an abuse of discretion. Id. at 845-57. Even ignoring the district court's wrongful application of reliability criteria to make a qualification determination, itself reversible error, the Eleventh Circuit held that it would still be obliged to reverse since the district court imposed "too high" of an admissibility standard on expert qualifications. Id. at 852-54; see also Adams v. Lab'y Corp. of Am., 760 F.3d 1322, 1335 (11th Cir. 2014) (rejecting the district court's reasoning that would "seemingly bar all expert medical testimony unless the expert has somehow recreated the same conditions that the defendant was under").

In conducting the Daubert inquiry, each of the three analytical prongs – including qualifications – must be "assessed in reference to the matter to which the expert seeks to testify – i.e., to the task at hand." Moore, 995 F.3d at 854 (internal quotations and citation omitted). To be qualified, the tendered expert must have the requisite expertise relevant to the "task at hand." Id. at 854-55. "At the fringes," defining the "task at hand" will be outcome determinative, and it is of course "in the nature of the Daubert inquiry that the proponents of expert testimony will seek the broadest definition of the task at hand, while the opponents . . . will seek to narrow it." Id. at 855.

That said, "the proffered expert must meet not only the basic qualification requirements, but also be qualified specifically in the area on which he or she proposes to testify." Dillon v. Sunbelt Rentals, Inc., 464 F. Supp. 3d 1333, 1338 (S.D. Fla. 2020). The Eleventh Circuit held that the district court did not abuse its discretion by excluding an expert whose academic work related more to plant pathology and botany than to chemistry when the issue subject to expert testimony was whether the chemical structure of a substance was "substantially similar" to a Schedule I drug.

U.S. v. Brown, 415 F.3d 1257, 1268-69 (11th Cir. 2005) ("Though we recognize that Steele does not have experience in chemistry, we can find no abuse of discretion in light of the fact that Steele has only worked with [the substances] 'on isolated projects' and that 'he does not possess a license to work with controlled substances.'"). Another court found that a mechanical engineer with no experience with refuse collection or garbage-truck design was unqualified to give expert opinion testimony on whether the defendant's garbage truck was defectively designed. Beam v. McNeilus Truck and Mfg., Inc., 697 F. Supp. 2d 1267, 1275-78 (N.D. Ala. 2010); see also Roper v. Kawasaki Heavy Indus., Ltd., No. 13-CV-03661, 2015 WL 11236553, at *4-5 (N.D. Ga. June 29, 2015) (finding that a mechanical engineer was likely unqualified to give expert testimony regarding a motorcycle voltage regulator even though the court had little doubt that he was a highly skilled and well-trained mechanical engineer and former automotive technician with experience working with that component in cars); but see Thomas, 2005 WL 6133409, at *6 ("[I]t is an abuse of discretion . . . to exclude expert testimony solely on the ground that the witness is not qualified . . . because the witness lacks expertise in specialized areas that are directly pertinent to the issues in question, if the witness has educational and experiential qualifications in a general field related to the subject matter of the issue in question.").

Here, Edwards is a materials scientist and engineer with over forty years' experience in conducting failure analyses of various materials. (Doc. 61 at 1); (Doc. 63-5 at 28). Edwards received a Bachelor of Science in materials science and engineering from North Carolina State University and studied for three years in its Mechanical Engineering Graduate Program. (Doc. 52-4 at 22). He was also "mentored by a failure analyst who was trained at NASA and then got a Ph.D. in material science in failure analysis later on." (Doc. 63-5 at 28). Defendants point out Edwards' lack of "any specific work on polymer liner in hips before this case, (Doc. 52-2 at 13),

and that he has not performed "a failure analysis regarding the polyethylene liner of the acetabular cup used in total hip replacement surgery," (id. at 15). (See Doc. 52 at 10; Doc. 65 at 3-4). However, Edwards has experience conducting failure analyses of medical device implants, including for total hip replacement systems. (Doc. 63-5 at 4-5, 25-26). He also has extensive experience, both educationally and professionally, analyzing and studying plastics, including polyethylene. (See Doc. 52-2 at 9, 20).

Defendants' attempts to narrow the subject matter about which Edwards must be qualified to testify are unavailing. Moore, 995 F.3d at 855 ("It is in the nature of the Daubert inquiry that the . . . opponents of [expert testimony] will seek to narrow [the definition of the task at hand]"). Mr. Edwards' "task at hand" was to evaluate Ms. Ahmed's failed hip implant and determine a cause of failure. (See Doc. 61 at 5-6). His mechanical engineering background and decades of experience conducting failure analyses, including of medical devices and of hip implants specifically, meant that this subject matter was "sufficiently within his expertise." Maiz, 253 F.3d at 665. That Edwards has "never analyzed a polyethylene (i.e., plastic) hip implant liner prior to being retained in this case," (Doc. 52 at 6), is of little moment given that the Eleventh Circuit has "explicitly disclaimed" a rule that "an expert witness is qualified to testify regarding a the cause of an injury only if he personally has used the allegedly defective product," Moore, 995 F.3d at 854; see also Hendrix, 255 F.R.D. at 585 ("[T]he standard for determining an expert's qualifications to testify on a given topic is not stringent. So long as the witness is minimally qualified, objections to the level of the expert's expertise go to credibility and weight, not admissibility."). Thus, the Court finds that Mr. Edwards is qualified to opine on whether the medical device at issue is defective.

B. Mr. Edwards' Design Defect Opinions are Generally Reliable, but he may not Testify as to Alternative Design Theory

i. Mr. Edwards' Design Defect Opinions are not Excludable Based on Inadequate Testing

When evaluating the reliability of expert opinion, the district court must consider "whether the reasoning or methodology underlying the testimony is scientifically valid and whether the reasoning or methodology properly can be applied to the facts in issue." Frazier, 387 F.3d at 1261-62 (alteration adopted). To evaluate the reliability of this proposed testimony, the trial judge is to assess: (1) whether the expert's theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential error rate of the particular scientific technique and the existence and maintenance of standards controlling the technique's operation; and (4) whether the technique is generally accepted in the scientific community. Daubert, 509 U.S. at 593-94; see also Frazier, 387 F.3d at 1262 ("The same criteria that are used to assess the reliability of a scientific opinion may be used to evaluate the reliability of non-scientific, experience-based testimony.") (citing Kumho Tire, 526 U.S. at 152). This inquiry is a flexible one whose focus is on the principles and methodology underlying proposed testimony and not the conclusions that they generate. Daubert, 509 U.S. at 594-95. Further, the factors are illustrative, not exhaustive, and not all of them will apply in every case. Frazier, 387 F.3d at 1262.

Defendants argue that Edwards' design defect opinions should be excluded because they are not the product of objective scientific testing or methodology. (Doc. 52 at 11-15). Defendants cite multiple cases for the proposition that "[a]bsent testing, an expert's opinions are mere 'observations' and 'impressions' that do not constitute a reliable scientific methodology." (Id. at 12) (citing Bushore v. Dow Corning-Wright Corp., No. 92-CV-344, 1999 WL 1116920, at *3

(M.D. Fla. Nov. 15, 1999) and Chapman v. Maytag Corp., 297 F.3d 682, 688 (7th Cir. 2002) ("Personal observation is not a substitute for scientific methodology and is insufficient to satisfy Daubert's most significant guidepost.")). Specifically, Defendants take issue with the fact that Edwards' design-defect opinions are based "solely on his visual, nondestructive examination and measurements of the implant components." (Doc. 52 at 12) (citing 52-2 at 4, 26-28). Further, Edwards said in his deposition that the polyethylene liner at issue "has some special qualities from the IR [infrared spectrometry] that will require some destructive testing." (Doc. 52-2 at 21). Later, Edwards seemingly conceded that he "could learn much more with destructive testing." (Doc. 52-2 at 25). Plaintiff counters that Edwards was confined to non-destructive testing[3] and that he never testified that more specificity was needed for his analysis but that destructive testing "is more of the type needed for an academic paper, rather than the failure analysis he performed."[4] (Doc. 61 at 9) (citing Doc. 63-5 at 10-12, 29-30).

However, "[p]hysical testing is not an absolute prerequisite to the admission of expert testimony." Hendrix, 255 F.R.D. at 586; Williams v. Tristar Products, Inc., 418 F. Supp. 3d 1212, 1221 (M.D. Ga. 2019) (same). Expert opinion predicated solely on the expert – with thirty years of knowledge and experience as a chemist – visually comparing representations of the chemicals at issue is admissible despite fulfilling only one of the four Daubert factors. Brown, 415 F.3d at 1267 (holding that the method's general acceptance was enough to make the testimony admissible

[3] According to Plaintiff, Edwards "was confined to non-destructive testing because the Defendant did not want the device destroyed prior to having an opportunity to inspect it" and that the Hip Implant was not returned before the deadline for his report. (Doc. 61 at 9 n.1); (see Doc. 52-2 at 25) ("I didn't get the parts back until after my report so . . . . ."). Defendants reply that Edwards testified at his deposition that Plaintiff's counsel "didn't want any destructive testing," (Doc. 52-2 at 6), and that Edwards never followed up on the possibility with Plaintiff's counsel. (Doc. 65 at 5 n.3). The Court need not concern itself with this dispute given that it finds that Edwards' design defect opinions are scientifically reliable even though he did not destructively test the Hip Implant.

[4] On the contrary, it appears from Edwards' deposition transcript that he was discussing the purpose and results of his infrared spectrograph testing – not destructive testing – in the portions Plaintiff cites. (See Doc. 63-5 at 10-12, 29-30).

even though the other three Daubert factors were absent). An expert's failure to perform any tests other than fractography to reach a plastic molding opinion is a matter for cross-examination at trial. Hendrix, 255 F.R.D. at 586; see also Clay v. Ford Motor Co., 215 F.3d 663, 668 (6th Cir. 2000) ("The district court, in its discretion, could have decided that Richardson's failure to test his theories went to the weight of his testimony regarding the defects in the Bronco II, not to its admissibility."). Failure to perform testing on the incident product may not provide a basis for exclusion when the otherwise qualified expert is familiar with the kind of product at issue and details his visual examination of the incident product. Williams, 418 F. Supp. 3d at 1222. Likewise, a well-established engineering methodology may be sufficiently reliable to render admissible testimony on whether a product is unreasonably dangerous based on a design defect. Jones, 2019 WL 1254814, at *5; Covas v. Coleman Co., Inc., No. 00-CV-8541, 2005 WL 6166740, at *5-6 (S.D. Fla. May 22, 2008) (denying that an expert's testimony is unreliable because he did not physically examine or run any tests on the incident product).

The Court finds that Edwards' design defect opinions are scientifically reliable despite his lack of destructive testing of the incident product. Edwards examined and measured the Hip Implant's ball and liner, including "witness marks" on each; reviewed literature published by Defendants and various other research papers "that have identified the problem with liner disassociation and their testing"; conducted an infrared spectrograph of the liner material; and created a replica – a "negative mold impression" – of the liner to better visualize (under a microscope) some of the liner's characteristics. (Doc. 63-5 at 7-10, 16-17). Edwards bases his conclusions regarding product defect on the results of these efforts. (E.g., Doc. 52-4 at 14) ("The recurring incidence of liner dissociation indicates that the locking mechanism between the Altrx liner and the Pinnacle acetabular cup is inadequate to hold the liner in place during impingement and extremes of range

of motion."). Defendants do not attack infrared spectroscopy as an unreliable discipline, and, in any event, "[u]se of infrared spectroscopy is a common and recognized scientific tool used to determine the chemical composition of materials." Int'l Paper Co. v. IFS Indus., Inc., No. 2:11-CV-02865, 2013 WL 12284519, at *3 (W.D. Tenn. June 11, 2013). Even when the expert did not perform testing on the incident product, a well-established engineering methodology may be sufficiently reliable to make testimony on whether a product is unreasonably dangerous based on a design defect admissible. Jones, 2019 WL 1254814, at *5. Physical testing is not an absolute prerequisite to admitting expert testimony, Hendrix, 255 F.R.D. at 586, nor is it necessary that the proponent satisfy more than one of the Daubert factors to show that the expert's opinion is scientifically reliable, Brown, 415 F.3d at 1267. Accordingly, the Court finds that Edwards' design defect opinions are reliable.

Defendants also attack Edwards' opinions as unscientific resting on a "selective and incomplete review of the literature. (Doc. 52 at 13). Specifically, Defendants point out that Edwards did not rely on any documents that: were not publicly available; were from the product design history file; concerned testing or the chemical formula of the polyethylene liner; or involved "registry data concerning THA components of any type." (Id.) (citing 52-2 at 29-30, 38). Yet Edwards' report cites the 25 sources that he reviewed while investigating the product failure, including a variety of academic papers and published industry reports. (See Doc. 52-4 at 4-7). Even if the Court were to conclude that these sources were somehow inadequate for the purpose of supporting Edwards' conclusions, "[w]here an expert otherwise reliably utilizes scientific methods to reach a conclusion, lack of textual support may go to the weight, not the admissibility of the expert's testimony." Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 354 (5th Cir. 2007)

(internal quotations and citation omitted) (noting also that a "contrary requirement would effectively resurrect a Frye-like bright-line standard").

Finally, Defendants argue that that Edwards' conclusions amount to "unauthorized conclusions from limited data" because "none of the papers he considered actually concluded that the Pinnacle hip replacement device or any component parts (including the Altryx liner at issue) were defective." (Doc. 52 at 14) (citing McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1247-48 (11th Cir. 2005)). But, as detailed above, Edwards' literature review was part of a wider technical process, which also included examining and measuring the Hip Implant's ball and liner; conducting an infrared spectrograph of the liner material; and creating a replica to better visualize some of the liner's characteristics. (Doc. 63-5 at 7-10, 16-17); (Doc. 61 at 10) ("Mr. Edwards is an engineer whose expertise was engaged to make an independent assessment, not simply repeat the opinions of others."). Moreover, an expert need not "back his or her opinion with published studies that unequivocally support his or her conclusions." Knight, 482 F.3d at 354.

ii. Mr. Edwards may not Reliably Testify as to Alternative Design Theory

A frequently used and effective methodology for proving that an alternative design is available and safer than what is being challenged is building the alternative design (or using a mathematical or computer model to reveal the same information). Crawford v. ITW Food Equip. Grp., 977 F.3d 1331, 1340 (11th Cir. 2020). Not testing alternative designs for an allegedly defective product may provide a basis for the district court to properly conclude that the expert's methodology is not scientifically reliable. McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1256-57 (11th Cir. 2002) (upholding the district court's exclusion of an expert that did not test alternative designs for the product; did not talk to medical personnel; was unable to cite scientific literature supporting

his theories; and did not consider or test possibilities for failure that could have come from sources outside the product).

Likewise, when the expert did not conduct any experiments to test the feasibility or capabilities of the alternative designs he proposes but cites as the basis for the lack of testing his years of experience in the broader field, his opinions regarding alternative designs are excludable. McCreless v. Global Upholstery Co., Inc., 500 F. Supp. 2d 1350, 1357-58 (N.D. Ala. 2007); see also Thurmond v. Fed. Signal Corp., No. 16-CV-1520, 2018 WL 9490352, at *4 (N.D. Ga. 2018) (holding that the failure to conduct any analysis of the alternative designs or produce any diagrams or perform any calculations that would illustrate the feasibility of the alternative designs was fatal to the proffered alternative design opinions); Green v. Five Star Mfg., Inc., No. 2:14-CV-449, 2016 WL 1243757, at *9 (N.D. Ala. Mar. 30, 2016) (ruling that "mere observations" and failure to test a proposed alternative design, cite another's testing of the design, or explain the source of the conclusions underpinning the proposed design do not constitute a reliable methodology from which an expert opinion as to a safer alternative design can be formed). After all, "the proper methodology for proposing alternative designs includes more than just conceptualizing possibilities." Watkins v. Telsmith, Inc., 121 F.3d 984, 992 (5th Cir. 1997). However, "where the proposed alternative design has been produced and put to practical use in the industry, the expert does not need to personally test it to satisfy Daubert." Moncrieffe v. Clark Equip. Co., No. 06-CV-22644, 2008 WL 11333222, at *8 (S.D. Fla. July 23, 2008).

Edwards' expert report contains multiple alternative design proposals. (See Doc. 52-4 at 10, 11, 14). Edwards wrote, "It is clear that more material, oriented perpendicular to the pole-equator direction, is needed in the anti-rotation tabs." (Id. at 10). He proposed that "[m]ore tabs and/or larger tabs could serve to retain the liner within the cup, preventing dissociation." (Id. at 11). In

the Report's "Conclusions" section, Edwards suggested that "[t]he anti-rotation tabs on the liner can be made larger and/or increased in number to as many as twelve" and that "[t]he shape of the anti-rotation tabs can be changed to remove the mechanical advantage of the sloped sides." (Id. at 14).

Edwards stated in his deposition that he was "not in the business" of testing proposed alternative designs. (Doc. 52-2 at 62). He conceded that he "[hasn't] proposed an alternative design," (id. at 64), and that "he [has] no alternative designs," (id. at 67). Moreover, although Edwards believes stronger or more tabs would have prevented the liner from deforming, he was unable to reliably point to any specific competitor design that implemented more tabs. Nor was there any evidence that the competitors had stronger tabs that withstood impingement. In other words, there is insufficient evidence that Edwards' theories on alternative design have been tested and succeeded. Accordingly, Edwards is excluded from testifying at trial regarding any alternative design proposals that may have been available to Defendants in manufacturing the allegedly defective Hip Implant.[5] (See Doc. 52-4 at 14). It appears from the deposition transcript and Edwards' Daubert hearing testimony that he merely "conceptualiz[ed] possibilities" when suggesting changes to the anti-rotation tabs, which are an insufficiently reliable basis for proposing alternative designs. See Watkins, 121 F.3d at 992.

Edwards' report indicates that there are 12 openings into which the tabs could potentially fit. (Doc. 52-4 at 9); (Doc. 61 at 16). Plaintiff concludes, "The manufacturer obviously contemplated up to twelve tabs when designing the cup." (Doc. 61 at 16). "It follows that if both the device's previous iterations and its competitors were able to increase the product's resistance to liner dissociation, and the device's current design contemplates such improvements (twelve tab

[5] This finding does not prohibit Mr. Edwards from testifying as to why the product was allegedly defective, i.e., the tabs were insufficient to prevent the liner from deforming.

openings), that these options were available and known to Defendant. Mr. Edwards should be permitted to testify to these safer, available alternative designs in support of Plaintiff's AEMLD claim." (Id.). The Court disagrees as to Edwards' ability to testify regarding a theoretical alternative design when applicable case law suggests that the failure to test a proposed alternative design or cite another's testing of the design is fatal to the admissibility of said testimony. This is not a case "where the proposed alternative design has been produced and put to practical use in the industry" because Plaintiff does not submit that the manufacturer ever actually included twelve tabs when designing the cup. See Moncrieffe, 2008 WL 11333222, at *8.

However, this is not to say that Mr. Edwards is prohibited from testifying as to Count Five (Breach of Implied Warranty). Unlike AEMLD[6] and negligent design[7] claims, because breach of implied warranty claims do not require proof of a proposed alternative design,[8] there is no reason why Mr. Edwards could not testify that the Hip Implant was defective for purposes of Plaintiff's breach of implied warranty of merchantability claim.

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[6] "In order to prove that a product is defective for purposes of the AEMLD [Alabama Extended Manufacturer's Liability Doctrine], a plaintiff must prove that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the product. The existence of a safer, practical, alternative design must be proved by showing that:

(a) The plaintiff's injuries would have been eliminated or in some way reduced by use of the alternative design; and that

(b) taking into consideration such factors as the intended use of the product, its styling, cost, and desirability, its safety aspects, the foreseeability of the particular accident, the likelihood of injury, and the probable seriousness of the injury if that accident occurred, the obviousness of the defect, and the manufacturer's ability to eliminate the defect, the utility of the alternative design outweighed the utility of the design actually used." Gen. Motors Corp. v. Jernigan, 883 So. 2d 646, 662 (Ala. 2003) (internal quotations and citations omitted and alteration adopted).

[7] To prove defectiveness in a negligent design defect claim under Alabama law, "a plaintiff must prove that a safer, practical, alternative design was available to the manufacturer at the time it manufactured its product." Richards v. Michelin Tire Corp., 21 F.3d 1048, 1056 (11th Cir. 1994).

[8] See, e.g., Garrison v. Sturm, Ruger & Co., Inc., 322 F. Supp. 3d 1217, 1224-32, 1233-36 (N.D. Ala. 2018) (ruling that the plaintiff's AEMLD and negligence claims, but not implied warranty, must fail as a matter of law after being unable to prove the existence of a feasible, safer alternative design).

iii. Mr. Edwards' Manufacturing Defect Opinions are not Impermissible Ipse Dixit

"[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." Cook ex rel. Est. of Tessier v. Sheriff of Monroe Cnty., 402 F.3d 1092, 1111 (11th Cir. 2005). According to Defendants, Mr. Edwards' manufacturing defect opinions are pure *ipse dixit*, "based on speculation, conjecture and inference, rather than reliable principles and methods." (Doc. 52 at 17-18) (internal quotations and citation omitted and alteration adopted). For the reasons explained above, while Edwards may not reliably testify as to alternative design theory, his defect opinions are "the product of reliable principles and methods" and reflect "a reliable application of the principles and methods to the facts of the case." See Fed. R. Evid. 702 (c-d). Putting aside Mr. Edwards' alternative design proposals, his report includes the following conclusions:

> 2. The recurring incidence of liner disassociation indicates that the locking mechanism between the Altrx liner and the Pinnacle acetabular cup is inadequate to hold the liner in place during impingement and extremes of range of motion. This lack of restraint between the cup and the liner is a defect in either manufacturing or design.
>
> 3. The anti-rotation tab is defective. Sheared anti-rotation tabs indicate a design defect.

(Doc. 52-4 at 14). The report's "Examination and Observations" and "Discussion" sections provide much more specific results from Edwards' examination of the Hip Implant, replete with appropriate citations to relevant authorities. (Id. at 8-13). Edwards' deposition included the following exchange:

> Q: What evidence or data are you basing your hypothesis that there was a manufacturing defect on?
>
> A: Well, you have testified about CAD drawings and history and specifications and FDA regulations and technical drawings. And so if all those things are as they should be, then the alternative has to be a manufacturing defect, maybe too much plasticizer, too much antioxidant.

(Doc. 52-2 at 55). Like many (if not most) scientists, Mr. Edwards does not have direct evidence of a manufacturing or design flaw in the Hip Implant but instead employed inductive reasoning to reach the hypothesis that the product was defective in either manufacturing or design. (See Doc. 52-2 at 56-57); see U.S. v. Neris, No. 10-CR-2604, 2012 WL 13081447, at *1 (D.N.M. Feb. 17, 2012) ("His assessment is logical, following a straight-forward path of inductive reasoning; and therefore, conforms to the standards articulated in Daubert and its progeny."). "So what I'm hearing you say, as you sit here today, you don't have any evidence of a manufacturing flaw in these products; is that true? You just have a hypothesis." (Doc. 52-2 at 56-57). Such is the essence of the scientific method. Further, "[a]s circumstantial evidence, [the expert's] data and testimony need not prove the plaintiff's case by themselves; they must merely constitute one piece of the puzzle that the plaintiff endeavor[s] to assemble before the jury." City of Tuscaloosa, 158 F.3d at 565; cf. Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000) ("The expert need not have an opinion on the ultimate question to be resolved by the trier of fact in order to satisfy" the Daubert criterion for helpfulness).

And while Defendants do not attack Mr. Edwards' expert planned testimony as unhelpful, the Court that it has no problem finding that his testimony would "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). "The touchstone of this inquiry is the concept of relevance." Prosper v. Martin, 989 F.3d 1242, 1249 (11th Cir. 2021). Expert testimony is relevant if it logically advances a material aspect of the proposing party's case. Allison, 184 F.3d at 1312. "Expert testimony is admissible if it concerns matters that are beyond the understanding of the average lay person." Frazier, 387 F.3d at 1262. Here, the composition of hip implants and their tendency to fail or not fail under certain conditions is certainly beyond the understanding of the average lay person, and Edwards' testimony would logically advance

Plaintiff's efforts to prove that the Hip Implant was "not suitable or fit for the ordinary purpose for which [hip implants are] used" and that Ms. Ahmed was "caused harm by the breach of the promise or warranty." See 2 Ala. Pattern Jury Instr. Civ. 32.21 (3d ed.). As such, it will assist the trier of fact, "through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." City of Tuscaloosa, 158 F.3d at 562.

C. Mr. Edwards' Non-Medical Causation Opinions Are Not Excludable

Defendants also ask that the Court exclude Edwards' causation opinions because he is not qualified to offer medical causation opinions, and even if he were qualified to offer medical causation opinions, "his opinions would still be inadmissible because he failed to meaningfully account for far more likely factors and causes of Ms. Ahmed's alleged injuries." (Doc. 52 at 18-19). Certainly, engineers are not qualified to offer opinions as to medical causation. Bowers v. Norfolk S. Corp., 537 F. Supp. 2d 1343, 1377 (M.D. Ga. 2007) ("Dr. Trimble may testify as to the effect of locomotive vibration on the human body and the types of injuries that may result from exposure to various levels of vibration. However, he may not offer an opinion as to whether the vibration in Plaintiff's locomotive caused Plaintiff's injuries. Such an opinion requires the identification and diagnosis of a medical condition, which demands the expertise and specialized training of a medical doctor."). But "Edwards does not offer medical causation opinions; he offers opinions on the reasons for the failure of the device." (Doc. 61 at 13). Defendants reply that this is a distinction without a difference because "[w]hether (and, if so, how) a purportedly defective hip implant failed necessarily implicates the human body, anatomical forces, pre-existing conditions, and the practice of medicine – subjects plaintiff appears to concede are outside Mr. Edwards' expertise." (Doc. 65 at 7).

Edwards concludes that the Hip Implant malfunctioned because the locking mechanism between the Altrx liner and Pinnacle cup was inadequate to hold the liner in place after impingement occurred. (Doc. 52-4 at 14). This is a product defect opinion from a materials scientist and engineer with over forty years' experience in failure analysis of various materials. (see Doc. 61 at 1). It is not a medical causation opinion. And, as explained *infra*, an expert opinion regarding medical causation is not necessary under the facts/allegations of this case.

Defendants also allege that Edwards "failed to consider – much less meaningfully rule out – other far more likely causes of Ms. Ahmed's alleged injuries, such as impingement . . . ." (Doc. 52 at 20). Plaintiff points out in response that Edwards expressly acknowledged that impingement most likely caused the dissociation, (Doc. 63-5 at 34), but that his opinion is that movement of the liner and the shearing of the tabs occurred after impingement, and that impingement would not have caused dissociation had the locking mechanism been stronger, (Doc. 61 at 14) (citing Doc. 63-5 at 33; Doc. 52-4 at 14). While Daubert admissibility rulings require that the trial court "conduct an exacting analysis of the proffered expert's methodology . . . it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech., 326 F.3d at 1341. The Court finds that Defendants' arguments go to persuasiveness, not admissibility.

D. Opinions that Mr. Edwards Revealed for the First Time at his Deposition May Come In

Under Rule 26(e)(1), "A party who has made a disclosure under Rule 26(a) . . . must supplement . . . its disclosure . . . in a timely manner if the party learns that in some material respect the disclosure . . . is incomplete or incorrect, and the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A) (emphasis added); Guerva v. NCL (Bahamas) Ltd., 920 F.3d 710, 718 (11th

Cir. 2019) (quoting same). For Rule 26(a)(2)(B) experts,[9] the party's duty to supplement extends to both to information in that expert's report and information given during the expert's deposition. Fed. R. Civ. P. 26(e)(2). "Any additions or changes to this information must be disclosed by the time the party's pretrial disclosures under Rule 26(a)(3) are due." Id. If the information in the change or addition to the disclosure is comparable and does not alter the expert's earlier disclosures, then no 26(e)(2) violation occurred. Morrow v. Allstate Indem. Co., No. 5:16-CV-137, 2020 WL 11629213, at *11 (M.D. Ga. June 1, 2020). Rule 26(e)(2)'s purpose is "to put the opposing party on notice as to what testimony the expert will present at trial." Id. at *12. In this case, the pretrial disclosure deadline and, therefore, the deadline for supplementing information in either the expert report or given during the expert's deposition is no later than 21 days prior to the date of the final pretrial conference, which is currently scheduled for March 7, 2024. (See Doc. 20).

Here, Edwards discussed at his deposition the following that were not included in his expert report: (1) his opinion that "[t]he plastic in the liner is too deformable," (Doc. 52-2 at 8); and (2) a free body diagram to calculate the forces exerted on the Hip Implant, (Doc. 52-2 at 58). As to both, the Court cannot see how Defendants' objections hold water. (See Doc. 52 at 21-22). First, both were disclosed at a deposition – "during the discovery process" – thereby obviating Plaintiff's supplementation obligation. See Fed. R. Civ. P. 26(e)(1)(A). Defendants' citation to the District of South Carolina case excluding certain of Edwards' opinions in unrelated litigation is inapposite as that order concerned opinions not disclosed during the discovery period. See Quinton v. Toyota

[9] Per Rule 26(a)(2)(B), "if the [expert] witness is one retained or specially employed to provide expert testimony in the case," the proffering party must accompany the disclosure of that expert's identity with a written report prepared and signed by the expert. See Fed. R. Civ. P. 26(a)(2)(B). Considering Edwards' expert witness report, (Doc. 52-4), and that he was retained to provide expert testimony in support of Ms. Ahmed's claims, he is clearly an "expert whose report must be disclosed under Rule 26(a)(2)(B)." Fed. R. Civ. P. 26(e)(2).

Motor Corp., No. 1:10-CV-02187-JMC, (Doc. 208) (D.S.C. June 7, 2013) ("Plaintiff counters that the failure to provide a supplemental report was because Defendants first disclosed (and Plaintiff first learned of) the existence of the test airbag three days before the close of discovery . . . ."). Even if the information in the added statements was not comparable to that in his report – it was – supplementation was not necessary under 26(e)(2) because disclosure was made at Mr. Edwards' deposition, before the pretrial disclosure deadline. See Morrow, 2020 WL 11629213, at *11; see also State Farm Mut. Auto. Ins. Co. v. Larocca, No. 8:21-CV-2536, 2023 WL 6294262, at *1 (M.D. Fla. Aug. 28, 2023) ("Plaintiffs' experts offered no new opinions and did not identify materials Defendants did not already possess . . . .").

Second, neither Mr. Edwards' opinion that the plastic in the liner is too deformable nor the free body diagram calculations differ "in some material respect" from the opinions disclosed in his report, and therefore do not constitute new information sufficient to trigger the supplementation obligation under 26(e)(1). See Fed. R. Civ. P. 26(e)(1)(A). With respect to the free body diagram, Edwards included in his report a discussion of forces on Hip Implant components. (See Doc. 52-4 at 11-12). "Edwards' testimony about his free body diagram is simply an explanation of his methodology and how he conducted the calculations described in his report, rather than the introduction of a new opinion." (Doc. 61 at 18). Accordingly, no supplementation is needed for merely explaining an opinion that Edwards already detailed in his report. With respect to the opinion on the plastic liner being too deformable, Edwards wrote in his report, "Damage to the liner consists of significant permanent deformation of the lip and the liner's anti-rotation tabs." (Doc. 52-4 at 8). He mentions deformation of the liner three other times in the report. (Id. at 13, 20). "Rule 26(e) envisions supplementation when a party's discovery disclosures happen to be defective in some way so that the disclosure was incorrect and incomplete, and therefore,

misleading." Myers v. Sears Authorized Hometown Stores, Inc., No. 3:12-CV-111, 2013 WL 12345260, at *1 (N.D. Fla. Apr. 12, 2013). Edwards' opinion that the plastic in the liner is too deformable hardly renders his prior disclosure misleading to the point of necessitating supplementation. Certainly, an expert witness's report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). But buying Defendants' argument in their Reply would make Rule 26(e)'s supplementation obligation surplusage. (See Doc. 65 at 9) ("But Rule 26 does not include an exception for 'simple' expert work; rather it expressly requires "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming them.") (emphasis included); see also Chickasaw Nation v. U.S., 534 U.S. 84, 93 (2001) ("The Court has often said that every clause and word of a statute should, if possible, be given effect.") (internal quotations and citations omitted and alteration adopted). And Plaintiff had no duty to supplement Edwards' expert report for the multiple reasons detailed above. Therefore, the Court will not exclude the opinions Edwards offered for the first time at his deposition.

Accordingly, Defendants' Motion to Exclude Opinions of Richard Edwards, (Doc. 51), is **GRANTED** to the extent that Mr. Edwards is prohibited from testifying as to any alternative design for the Hip Implant but is **DENIED** as to every other respect.

IV. ANALYSIS OF MOTION TO EXCLUDE OPINIONS OF DR. KENNETH SANDS

A. Dr. Sands is a Proper Rebuttal Witness

A rebuttal expert's task is different from that of an affirmative expert. Navelski v. Int'l Paper Co., 244 F. Supp. 3d 1275, 1302 (N.D. Fla. 2017). "A rebuttal expert, by definition, criticizes or rebuts the methodology and opinions of another expert." Id.; Marmo v. Tyson Fresh Meats, Inc.,

457 F.3d 748, 759 (8th Cir. 2006) ("The function of rebuttal testimony is to explain, repel, counteract or disprove evidence of the adverse party."); Fed. R. Civ. P. 26(a)(2)(D)(ii) ("[I]f the evidence is intended solely to contradict or rebut evidence on the same subject matter . . . .") (emphasis added). When a rebuttal expert's report responds to the opposing expert's opinions and controverts those opinions by reaching contrary conclusions, the rebuttal expert's report falls within the permissible scope of rebuttal evidence. Johnson v. Petsmart, Inc., No. 6:06-CV-1716, 2007 WL 3024029, at *2 (M.D. Fla. Oct. 15, 2007). "A rebuttal expert may cite new evidence and data so long as the new evidence and data is offered to directly contradict or rebut the opposing party's expert." Glass Dimensions, Inc. ex rel. Glass Dimensions, Inc. Profit Sharing Plan & Trust v. State St. Bank & Trust Co., 290 F.R.D. 11, 16 (D. Mass. 2013). Rebuttal expert testimony satisfies this standard as long as it repels the opposing party's affirmative expert testimony. Ohio State Troopers Ass'n, Inc. v. Point Blank Enters., Inc., No. 18-CV-63130, 2020 WL 1666763, at *3 (S.D. Fla. Apr. 3, 2020). The district court has broad discretion to decide what constitutes proper rebuttal evidence. Rent-A-Ctr., Inc. v. Canyon Television and Appliance Rental, Inc., 944 F.2d 597, 601 (9th Cir. 1991) (citing Datamatic Servs., Inc. v. U.S., 909 F.2d 1029, 1033 (7th Cir. 1990)); see also Lebron v. Royal Caribbean Cruises, Ltd., 2018 WL 3583002, at *2 (S.D. Fla. July 26, 2018) ("Courts are empowered to exercise their discretion and judgment in determining if a rebuttal expert addresses the same subject matter as the opposing party's initial expert report.").

Plaintiff designates Dr. Sands as a rebuttal witness to address Defendants' expert Dr. Steven Barrington's opinions. (See Doc. 62 at 4) ("It is offered to rebut Dr. Barrington's report; it is classic rebuttal opinion under the rule."); (Doc. 54-2 at 3) ("And then I ["Dr. Sands"] later learned that he wanted me to serve as a rebuttal for Dr. Barrington."). Defendants assert that Dr. Sands is an

improper rebuttal witness because he does not directly address or contradict Dr. Barrington's methodology, or conclusions. (Doc. 54 at 10).

Plaintiff counters that Dr. Sands' Report, (Doc. 63-6), is "intended solely to contradict or rebut evidence on the same subject matter identified by another party." (Doc. 62 at 3) (quoting Fed. R. Civ. P. 26(a)(2)(D)(ii)). "[I]t addresses the same subject matter (Ms. Ahmed's failed hip replacement), from the same perspective (that of an orthopedic surgeon) as does Defendants' expert, Dr. Barrington, and comes to a contradicting conclusion . . . [I]t is classic rebuttal opinion under the rule." Certainly, "disagreeing with a defense expert, alone, does not render a plaintiff's expert one sounding in rebuttal." Bell v. Progressive Select Life Ins. Co., No. 8:22-CV-1054, 2023 WL 5940306, at *2 (M.D. Fla. Sep. 13, 2023). However, having reviewed Dr. Sands' report, (Doc. 63-6), and that of Dr. Barrington, (Doc. 63-7) – whom Dr. Sands is proffered to rebut – the Court concludes that Dr. Sands' opinions satisfy the strictures of Rule 26(a)(2)(D)(ii).

At trial, Defendants will presumably call Dr. Barrington to testify and offer the opinions included in his report. (Doc. 54 at 8) (explaining that Dr. Barrington is a defense expert); see Fed. R. Civ. P. 26(a)(2)(B)(i) (explaining that a Rule 26(a)(2)(B) expert's report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them"). Dr. Barrington's opinion is that Ms. Ahmed's "medical procedures to repair and replace her right hip were primarily unsuccessful for patient-specific reasons and not as the result of any defect in the DePuy components used." (Doc. 63-7 at 5). Specifically, her significant spinal deformity and stiffness purportedly led to impingement of the femoral neck and consequently to early failure. (Id.). Thus, patient-specific factors were responsible for the Hip Implant's early failure. (Id.). Dr. Sands will then rebut Dr. Barrington's opinion that patient-specific factors were responsible by testifying that Ms. Ahmed's failed total hip replacement was "multifactorial." (Doc. 63-6 at 6). As

his report states, Dr. Sands "cannot exclude the device from being one of the major contributing factors to Mrs. Ahmed's failed total hip replacement." (Id. at 7). So, Dr. Sands will address the same conclusion as Dr. Barrington – whether patient-specific factors caused the Hip Implant to fail – and controvert it by deciding that it was not just Ms. Ahmed's anatomy that caused the Hip Implant to fail, but also the device itself. See Johnson, 2007 WL 3024029, at *2. This therefore serves "the permissible rebuttal function of counteracting the testimony of the opposing expert witness." U.S. v. Posey, 647 F.2d 1048, 1052 (10th Cir. 1981). By contradicting Dr. Barrington's opinion on the exact same issue, Dr. Sands' testimony is thereby admissible. See Fed. R. Civ. P. 26(a)(2)(D)(ii).

Dr. Sands may not testify in plaintiff's case-in-chief to establish medical causation. He may only testify to rebut Dr. Barrington. Nonetheless, as discussed *infra*, expert medical causation testimony is not necessary in this case because the Record does not reveal a genuine dispute that the Hip Implant's failure caused Plaintiff's injuries – only whether there was a defect in the Hip Implant that caused it to fail. Plaintiff tenders Mr. Edwards' testimony in aid of the latter purpose. (Doc. 61 at 13) ("Edwards . . . offers opinions on the reasons for the failure of the device.").

B. Dr. Sands' Rebuttal Opinions are the Product of a Reliable Methodology

i. Dr. Sands Reliably "Ruled In" Defect as a Cause of Ms. Ahmed's Injuries

"An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. The word "data" in Rule 702's requirement that the expert's testimony is based on sufficient facts or data is intended to encompass the reliable opinions of other experts. Fed. R. Evid. 702 Advisory Comm.'s Note to 2000 Amend. Further, while case reports alone cannot ordinarily reliably prove causation, they may support other proof of causation. Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1199 (11th Cir. 2002). Case reports

may also rule out other potential causes of the effect but do "not rule out the possibility that the effect manifested in the reported patient's case is simply idiosyncratic or the result of unknown confounding factors." Id. Of course, a foundation for admissibility is that the proposed expert testimony is supported by appropriate validation or "good grounds," based on what is known. Frazier, 387 F.3d at 1261 (quoting Daubert, 509 U.S. at 590).

Here, Dr. Sands bases his opinion that the cause of the failed Hip Implant was multifactorial on his review of Ms. Ahmed's medical records, depositions of relevant parties, medical case reports, Mr. Edwards' expert report, and his own experience with total hip arthroplasty. (Doc. 63-6 at 4-8). Per Dr. Sands' report, the "three variables that must align" to achieve a successful arthroplasty are "[t]he patient, the surgeon, and the implant." (Id. at 6). Dr. Sands' approach in this case was to review the aforementioned sources in light of these factors and his extensive experience to ascertain the cause of the Hip Implant's failure. (See Doc. 54-2 at 11). First, Dr. Sands is a board-certified orthopedic surgeon who estimated that he performs just shy of 900 joint replacements a year, about half of which are hip replacements. (Doc. 63-8 at 3). "Experts are permitted to draw conclusions from a set of observations that are based on their extensive and specialized experience." Woienski v. United Airlines, Inc., 383 F. Supp. 3d 1342, 1349 (M.D. Fla. 2019). Next, Dr. Sands began his report and deposition by acknowledging Ms. Ahmed's unique spino-pelvic issues – and Dr. Engerson's failure to account for the same – as predisposing the Hip Implant to impingement and dislocation. (Doc. 63-6 at 6) ("Spino-pelvic issues can lead to dislocations and impingement and should be addressed intra-operatively when taking into account implant positioning or implant selection."); (Doc. 54-2 at 11) ("She had a spinal-pelvic pathology that would make any operation difficult on her and she was very prone for dislocation.").

At that point, Dr. Sands considered the third potential cause of the Hip Implant's failure – defects in the Hip Implant. (Doc. 63-6 at 6-8). This is a variable that even Defendants' expert, Dr. Barrington, concedes "must align in order to achieve success." (Doc. 63-7 at 5). Dr. Sands predicated his opinion that he could not exclude defects in the Hip Implant from being one of the major contributing factors for Ms. Ahmed's failed total hip replacement on both case reports indicating higher dissociation rates of Pinnacle liners and Mr. Edwards' report. (Doc. 63-6 at 6-7).

Defendants attack Dr. Sands' reliance on case reports as impermissible because "they are not the kind of scientific materials on which experts would rely outside the courtroom." (Doc. 54 at 17). But Defendants overlook Dr. Sands' deliberate use of case reports and his acknowledgement of their relative weakness as a scientific source standing alone. Dr. Sands agreed that "[i]n the hierarchy of medical literature, case reports are generally considered to be low." (Doc. 54-2 at 24). Dr. Sands also recognized that unlike valid clinical or epidemiological studies, case reports are not subject to control. (Id. at 24-25); see also Rider, 295 F.3d at 1199 ("Even these more detailed case reports, however, are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert that they do because they report symptoms observed in a single patient in an uncontrolled context."). However, Dr. Sands explained in his deposition that the reason for case reports is to "sound . . . alarms" to "silo[ed]" surgeons and companies over medical device issues that merit more detailed scientific investigation. (Doc. 54-2 at 25-26). His report specifically cites and explains findings from multiple case reports that reveal relatively higher rates of Pinnacle liner dissociation. (Doc. 63-6 at 6-7). Dr. Sands contrasts those findings from a previous study showing the Pinnacle predecessor as "having one of the best [lever-out] strengths." (Id. at 7). The combination of these reports, the fact that impingement is not uncommon in total hip replacements nor unique to Johnson and Johnson implants, and Mr. Edwards' data regarding

"the Pinnacle poly liner locking mechanism" led to Dr. Sands' inability to exclude the Hip Implant itself from being one of the major causes of the Hip Implant's failure. (Id.) (noting also that "impingement is not uncommon and has been reported in as many as 56% of total hip replacements"). Accordingly, the numerous case reports, including those specific to the Depuy Pinnacle Cup, appropriately do not alone prove causation. Rider, 295 F.3d at 1199.

To be sure, Dr. Sands' rebuttal report cannot properly and does not prove causation – that's Mr. Edwards' job. All the same, given that the Court already held *supra* that Mr. Edwards' design defect opinions are generally reliable, Dr. Sands may rely on them in support of his refusal to rule out the Hip Implant itself as a major contributing factor for Ms. Ahmed's failed total hip replacement. See Fed. R. Evid. 702 Advisory Comm.'s Note to 2000 Amend. ("The term 'data' is intended to encompass the reliable opinions of other experts.").

ii. Dr. Sands Did Not "Rule Out" Any of the Three Variable as Potential Causes for the Hip Implant's Failure and Was Not Obligated to Do So

Differential diagnosis or etiology is a medical process of elimination in which the possible causes of a condition are considered and ruled out one-by-one such that one cause remains. Hendrix ex rel. G.P. v. Evenflo Co., Inc., 609 F.3d 1183, 1195 (11th Cir. 2010). It is a well-recognized scientific method that can provide a valid basis for medical causation opinions. Id. "A reliable differential analysis need not rule out all possible alternative causes, but it must at least consider other factors that could have been the sole cause of the plaintiff's injury." Chapman v. Procter & Gamble Distrib., LLC, 766 F.3d 1296, 1308-09 (11th Cir. 2014) (internal quotations and citation omitted and emphasis added). An expert's differential diagnosis testimony is unreliable when it fails to sufficiently explain why other potential causes have been ruled out. E.g., Jones v. Novartis Pharms. Corp., 235 F. Supp. 3d 1244, 1293-95 (N.D. Ala. 2017). Yet a differential diagnosis is not an absolute requirement to survive a Daubert challenge. Sampson v.

Carnival Corp., No. 15-CV-24339, 2016 WL 7377226, at *4 (S.D. Fla. Dec. 16, 2016) (clarifying that the Eleventh Circuit has never explicitly required this form of analysis); In re 3M Combat Arms Earplug Prods. Liab. Litig., No. 3:19-MD-2885, 2021 WL 830309, at *5 (N.D. Fla. Mar. 4, 2021) ("The fact that [the experts] did not formally perform more traditional differential diagnoses does not compel exclusion of their specific causation testimony."). Even outside of a strict differential diagnosis, "[e]limination of alternative possibilities is one method of arriving at a result reliably, but it is not the only method." Chisesi Bros. Meat Packing Co., Inc. v. Westchester Surplus Lines Ins. Co., No. 09-CV-6523, 2010 WL 3720465, at *4 (E.D. La. Sep. 9, 2010); Jackson v. Parker-Hannifin Corp., 645 F. Supp. 3d 577, 589 (S.D. Miss. 2022) (citing same).

Dr. Sands did not conduct a differential diagnosis in this case and was not required to do so. See Sampson, 2016 WL 7377226, at *4; In re 3M Combat Arms, 2021 WL 830309, at *5. Defendants admit as much: "This argument is at odds with Dr. Sands' clear testimony that the methodology he used to reach his causation opinion involved evaluating 'all of the factors,' which is akin to a differential diagnosis . . . Accordingly, he was required to apply that method faithfully . . . ." (Doc. 66 at 5). Both Dr. Sands and Defendants' expert, Dr. Barrington, agree that a successful arthroplasty necessitates the alignment of three variables: the surgeon, the implant, and patient-specific factors. (Doc. 63-6 at 6); (Doc. 63-7 at 5). Dr. Sands did not rule out any of these as potential causes; rather, his detailed concerns with respect to each factor undergird his conclusion that Ms. Ahmed's failed total hip replacement was multifactorial. (See Doc. 63-6 at 6-8). Nor did he find that all possible causes were causes. (See Doc. 54 at 20) (citing Guinn v. AstraZeneca Pharms. LP, 602 F.3d 1245, 1255 (11th Cir. 2010) ("Although the differential diagnosis technique is well accepted, a finding that all possible causes are causes does not appear to have gained general acceptance in the medical and scientific communities.") (internal quotations and citation omitted

and alteration adopted)). Again, Dr. Sands accepted Dr. Barrington's paradigm for the three variables necessary for a successful arthroplasty and his review of 24 sources, including Ms. Ahmed's medical records, Dr. Engerson's deposition testimony, case reports on the Depuy Pinnacle Cup, and Mr. Edwards' report, in combination with his extensive experience as an orthopedic surgeon conducting hundreds of hip implants a year, led him to refuse to rule out each variable as a potential cause of the Hip Implant's failure. (See Doc. 63-6). The report also expressly accounts for impingement as a contributing factor but explains why its occurrence in this case would not force the conclusion that a defective device was not at fault. (Id. at 7). Because Dr. Sands may reliably offer rebuttal expert testimony, Defendants' Motion to Exclude Opinions of Dr. Kenneth Sands, (Doc. 53), is **DENIED**.[10]

V. ANALYSIS OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

A. Summary Judgment is not Required on All of Plaintiff's Claims Even Though She Offers No Expert Evidence Regarding Medical Causation

"Regardless of the cause of action asserted, whether a defective product caused a plaintiff's injuries is an essential element of all product liability cases." Lowery v. Sanofi-Aventis LLC, 535 F. Supp. 3d 1157, 1175 (N.D. Ala. 2021). Medical expert testimony is essential to prove causation in a case in which the causation issue does not implicate natural inferences that a juror could make through human experience. Allison, 184 F.3d at 1320; Rivera v. Royal Caribbean Cruises Ltd., 711 F. App'x 952, 954 (11th Cir. 2017) (per curiam) ("When the causal link between alleged injuries and the incident at issue is not readily apparent to a lay person, expert medical testimony

[10] While Defendants do not contest Dr. Sands' testimony on these grounds, Dr. Sands, a board-certified orthopedic surgeon highly experienced with hip implants, is qualified to testify and his rebuttal testimony will assist the trier of fact by rebutting Dr. Barrington's opinion that the Hip Implant failed for patient-specific reasons and not as the result of any defect in the DePuy components used. See City of Tuscaloosa, 158 F.3d at 562 (organizing the Rule 702 criteria into three categories – qualifications, reliability, and helpfulness); Allison, 184 F.3d at 1312 ("Under the second prong of Daubert, the relevance requirement, the court must ensure that the proposed testimony is relevant to the task at hand, i.e., that it logically advances a material aspect of the proposing party's case.") (internal quotations and citation omitted and alteration adopted).

as to medical causation is typically required."); Kellner v. NCL (Bahamas), Ltd., No. 15-CV-23002, 2016 WL 4440510, at *1 (S.D. Fla. Aug. 22, 2016) ("Expert testimony is required to establish medical causation for conditions not readily observable or susceptible to evaluation by lay persons.").

Defendants say that all of Plaintiff's claims fail because "she cannot establish that a purported defect in the Pinnacle Altrx liner caused her hip replacement failure and alleged injuries." (Doc. 56 at 9). Plaintiff responds that she does not dispute that her claims require proof that a defective product caused her injuries; rather, Defendants' argument confuses the cause of the device's failure (i.e., whether it was a defective product) with the cause of Plaintiff's injuries, two distinct concepts. (Doc. 60 at 7) ("[I]t is undisputed that Ms. Ahmed's hip implant failed, had to be replaced, and that Ms. Ahmed later suffered infection and multiple revision surgeries subsequent to the initial failure . . . Thus, that the device's failure caused injury is clear and not in dispute.") (citing Doc. 56 at 7). Defendants implicitly concede the truth behind this difference by not disputing that the Hip Implant's failure caused Plaintiff's injury, instead focusing on whether proof of the product defect necessarily mandates the presentation of medical expert testimony. (See Doc. 67 at 1-5).

The Court agrees that the Record does not reveal a genuine dispute that the Hip Implant's failure caused Plaintiff's injuries. (See Doc. 60 at 7). Plaintiff underwent a right total hip arthroplasty on November 4, 2020, during which Dr. Engerson implanted her with Defendants' Pinnacle Altrx polyethylene liner, Pinnacle cup, and Biolix femoral head. (Doc. 56 at 7; Doc. 60 at 1-2; Doc. 63-1 at 3-4). She began physical therapy that same month. (Doc. 56-5 at 4). On or about December 25, some six weeks after surgery, Plaintiff, while getting up to walk, heard a "popping" sound come from her right hip that "sounded like a firecracker go off." (Doc. 63-2 at 7). Three days later, she visited an orthopedist and on January 25, 2021, "she told her doctor that

the hip pops and locks up sometimes." (Doc. 56-5 at 4). Plaintiff fell just prior to February 24, 2021. (Id.). During a visit with Dr. Engerson the next day, "radiographs revealed the hip was eccentrically located," (Doc. 56-4 at 4), and Dr. Engerson noted that she needed a "right hip poly exchange," (Doc. 56-5 at 4). Plaintiff underwent revision hip arthroplasty on March 1, 2021. (Doc. 56-4 at 4). While she tolerated the revision surgery, she underwent more surgery for acute infection that March, (Doc. 56-6 at 5), which was concentrated in the right hip, (Doc. 63-3 at 8-9). She experienced two subsequent dislocations of the right hip. (Doc. 56-4 at 4-5; Doc. 56-5 at 4). Plaintiff prays for "pain and suffering, mental anguish, medical extreme, physical disability, and anxiety" damages that supposedly proximately resulted from the Hip Implant's failure. (Doc. 1-2 at 9-10).

Therefore, even if whether the Hip Implant's failure caused Plaintiff's injuries was in dispute, it would be within a juror's purview that the damages over which Plaintiff sues resulted from the Hip Implant's failure and not some alternate cause. The Eleventh Circuit has generally cautioned against inferring that a temporal relationship proves a causal relationship. McClain, 401 F.3d at 1243 (explaining that the *post hoc ergo propter hoc* fallacy wrongfully assumes causality from temporal sequence); Guinn, 602 F.3d at 1254 ("Temporal proximity is generally not a reliable indicator of a causal relationship."). However, in this case it is certainly a "natural inference" that a juror could make through human experience that Plaintiff's revision hip arthroplasty, surgery for acute infection, and two subsequent hip dislocations – all involving damages concentrated in Ms. Ahmed's right hip – proximately resulted from the Hip Implant having failed. See Allison, 184 F.3d at 1320.

With respect to whether a defect in the Hip Implant caused Plaintiff's injuries, Defendants reply that whether the purported defect (i.e., the liner's inadequate locking mechanism) caused the

Hip Implant's failure "is a scientific question 'beyond the ken of lay jurors' because 'an implanted hip prosthesis is a complex and technical device,' and 'there may be innumerable reasons for the failure of the device and the need for a revision surgery that are wholly divorced from, and independent of, any defect . . . that the device may have had.'" (Doc. 67 at 3) (citing Hughes v. Stryker Sales Corp., No. 08-CV-0655, 2010 WL 1961051, at *4 (S.D. Ala. May 13, 2010)). As an initial matter, Defendants' reliance on Hughes is misplaced. Certainly, "Alabama law is crystal clear that the mere failure of a product does not presuppose the existence of a defect; instead, a defect must be affirmatively shown." Hughes, 2010 WL 1961051, at *4. However, Hughes' holding rested on the plaintiff's failure to proffer any expert opinions. Id. at *3 ("It is undisputed that [the plaintiff] made no expert disclosures and proffered no expert opinions that the prosthetic hip designed, manufactured and distributed by [the defendants] was defective in the manner alleged in the Complaint . . . ."). As a result, this Court concluded that those pieces of non-expert-opinion evidence plaintiff submitted were insufficient to raise a reasonable inference of a defect in her hip implant that caused her injury. Id. Here, by contrast, the Court has already found that Edwards' opinions that certain aspects of the Hip Implant were defective in either manufacturing or design – but not his theories as to any alternative design – may come in.

At bottom, Defendants are rearguing the point from their Motion to Exclude Opinions of Richard Edwards that as an engineer, he is unqualified to offer medical causation opinions, and given the dearth of any other expert opinions on the subject, Plaintiff "cannot adduce enough admissible evidence to create a genuine issue of material fact as to whether the alleged device defect caused their injuries." (Doc. 56 at 10) (citing Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1315 (9th Cir. 1995) (alteration adopted); (see Doc. 52 at 18-19) (maintaining that Mr. Edwards is not qualified to offer medical causation opinions). However, the Court held above that

Mr. Edwards, a materials scientist and engineer with over forty years' experience in failure analysis of various materials, offers product defect opinions, not medical opinions. Since Plaintiff may introduce Edwards' opinion that impingement would not have caused dissociation had the locking mechanism been stronger, (Doc. 61 at 14) (citing Doc. 63-5 at 33; Doc. 52-4 at 14), Plaintiff submits evidence "that ties the specific design defect . . . to the damages for which [she] seek[s] recovery." Cf. Nelson v. C.R. Bard, Inc., 553 F. Supp. 3d 343, 359 (S.D. Miss. 2021) (holding that the plaintiff's failure to cite like testimony or evidence warranted summary judgment in favor of the defendants on the design defect claim). That Dr. Sands will not testify as an affirmative expert on medical causation does not alter this conclusion. Moreover, that Dr. Engerson "explicitly disclaimed that the hip implant was defective in any manner," (Doc. 56 at 12), only reveals a genuine dispute over whether defects in the Hip Implant caused Plaintiff's injuries. Accordingly, summary judgment is not required on all of Plaintiff's claims even though she offers no expert evidence regarding medical causation.

B. Defendants are Entitled to Summary Judgment on Counts One (Product Liability/AEMLD) and Six (Negligence)

As explained above, Mr. Edwards is prohibited from testifying as to any alternative design for the Hip Implant in this case. According to Defendants, they are entitled to summary judgment on Counts One (Product Liability/AEMLD) and Six (Negligence) to the extent that they are predicated on a theory of design defect because Plaintiff cannot prove the existence of a safer, feasible, alternative design. (Doc. 56 at 13). Defendants are correct.

In an AEMLD case, the plaintiff has the burden of proving a design defect. Jernigan, 883 So. 2d at 662. To do so, a plaintiff must prove that "a safer, practical, alternative design was available to the manufacturer at the time it manufactured the product." Id. Likewise, negligent design defect claims under Alabama law necessitate the same proof. Richards, 21 F.3d at 1056. Here, given Mr.

Edwards' inability to testify as to alternative design theory and Plaintiff's proffering of no other experts or evidence regarding it, Plaintiff will be able to offer no evidence at trial to satisfy this burden. Absent evidence of a safer, practical, alternative design that would have eliminated or in some way reduced Plaintiff's injuries, summary judgment as to her AEMLD claim is proper. Phillips v. Am. Honda Motor Co., Inc., 238 F. App'x 537, 543 (11th Cir. 2007) (per curiam) ("With no evidence of a practical alternative design that would have eliminated or in some way reduced Plaintiff's injuries, the district court properly granted summary judgment under the AEMLD."); see also Borum v. Werner Co., No. 5:11-CV-997, 2012 WL 2047678, at *14 (N.D. Ala. June 6, 2012) ("With insufficient evidence regarding the proximate cause of the ladder's failure and the existence of a reasonable alternative design, Lowe's summary judgment motion on the AEMLD claim is due to be granted."). Similarly, to the extent Plaintiff's claim in Count Six (Negligence) is predicated on a theory of design defect, it must also fail. See Richards, 21 F.3d at 1056-57 (concluding that the failure to establish the existence of a practical, safer, alternative design meant that there was insufficient evidence for the plaintiff's negligent design defect claim). Accordingly, Defendants' Motion for Summary Judgment, (Doc. 55), is **GRANTED** as to Plaintiff's Count One (Product Liability/AEMLD) and Count Six (Negligence).[11]

[11] To the extent Plaintiff attempts to assert a separate cause of action for Defendants' alleged failure to examine, check, and verify the Hip Implant, (see Doc. 1-2 at 8-9), Defendants' Motion is also due to be granted. See Fed. R. Civ. P. 56(f) ("After giving notice and a reasonable time to respond, the court may . . . grant the motion on grounds not raised by a party."). In response to the plaintiffs' assertion of a "failure to test" the product in question claim, the Northern District of Alabama stated, "Plaintiffs have not directed the Court's attention to a single authority supporting the maintenance of such a claim under Alabama law, nor is the Court independently aware of such authority." McClain v. Metabolife Int'l, Inc., 193 F. Supp. 2d 1252, 1257 (N.D. Ala. 2002) (granting summary judgment with respect to the plaintiff's negligent "failure to test" claim as a separate cause of action and dismissing it with prejudice). In similar fashion, this Court is unaware of such authority under Alabama law, nor does Plaintiff point to any. As such, the entirety of Plaintiff's negligence claim in Count Six of the Complaint, (Doc. 1-2), fails as a matter of law.

C. Summary Judgment is Also Due as to Plaintiff's Claims in Count Two (Fraud/Suppression), Count Three (Failure to Warn and Defect), Count Four (Breach of Express Warranty), and Count Seven (Third-Party Beneficiary)

In her Response to Defendants' Motion for Summary Judgment, Plaintiff "concedes that she cannot establish manufacturing defect, failure to warn, fraud and breach of express warranty claims." (Doc. 60 at 16). The Court accepts Plaintiff's concession and **GRANTS** Defendants' Motion for Summary Judgment, (Doc. 55), as to Count Two (Fraud/Suppression), Count Three (Failure to Warn and Defect), and Count Four (Breach of Express Warranty). See, e.g., Lambert v. FedEx Ground Package Sys., Inc., No. 1:22-CV-740, 2024 WL 253622, at *2 n.3 (N.D. Ga. Jan. 23, 2024) ("The Court accepts the Plaintiff's concession and will grant summary judgment in the Defendant's favor on these claims."); Powers v. Catalent Pharm. Sols., LLC, No. 8:22-CV-1842, 2023 WL 8452051, at *6 (M.D. Fla. Dec. 6, 2023) (explaining that by conceding certain claims and only opposing summary judgment on others, the plaintiff has abandoned those claims, thereby entitling the defendant to summary judgment on them).

Unlike her claims in Count Two, Three, and Four, Plaintiff does not explicitly concede her standalone Third-Party Beneficiary claim in Count Seven. (See Doc. 60). However, by failing to address Defendants' argument that her third-party beneficiary claim is not cognizable under Alabama law, (see Doc. 56 at 20), Plaintiff impliedly abandoned it. Resol. Trust Corp. v. Dunmar Corp., 43 F.3d 587, 599 (11th Cir. 1995) ("[G]rounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned."); Powell v. Am. Remediation & Env't, Inc., 61 F. Supp. 3d 1244, 1252 n.9 (S.D. Ala. 2014) ("[W]here the non-moving party fails to address a particular claim asserted in the summary judgment motion but has responded to other claims made by the movant, the district court may properly consider the non-movant's default as intentional

and therefore consider the claim abandoned."). Accordingly, the Court also **GRANTS** Defendants' Motion for Summary Judgment, (Doc. 55), as to Count Seven (Third-Party Beneficiary).

D. Summary Judgment is Denied as to Plaintiff's Implied Warranty of Merchantability Claim in Count Five

As a preliminary matter, Plaintiff makes clear in her Response to Defendants' Motion for Summary Judgment, that her breach of implied warranty claim in Count Five of the Complaint "does not state a claim for [breach of] implied warranty of fitness for a particular purpose." (Doc. 60 at 13) (emphasis included). Thus, Plaintiff's claim in Count Five (Breach of Implied Warranty) must survive, if at all, as a breach of implied warranty of merchantability claim.

Defendants have not specifically moved for summary judgment as to Plaintiff's breach of implied warranty of merchantability claim. (See Doc. 56). Indeed, the Court rejects above Defendants' contention that "[a]ll of [P]laintiff's claims fail because she cannot establish that a purported defect in the Pinnacle Altrx liner caused her hip replacement failure and alleged injuries." (Doc. 56 at 9). And Defendants' memorandum elsewhere moves for summary judgment as to Count Five to the extent it alleges a claim for breach of implied warranty of fitness for a particular purpose, (see Doc. 56 at 16-19), a claim that Plaintiff subsequently clarified she does not seek.

That said, Defendants would not be entitled to a grant of summary judgment as to Plaintiff's breach of implied warranty of merchantability claim even if properly raised. Under the Alabama Commercial Code, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Ala. Code § 7-2-314(1). "Goods to be merchantable must be at least such as . . . [a]re fit for the ordinary purposes for which such goods are used." § 7-2-314(2). To establish a prima facie case for breach of the implied warranty of merchantability, the plaintiff must prove: (1) the existence of the warranty; (2) a breach

of that warranty; and (3) damages proximately resulting from that breach.[12] Bodie v. Purdue Pharma Co., 236 F. App'x 511, 522 (11th Cir. 2007) (citing Barrington Corp. v. Patrick Lumber Co., 447 So. 2d 785, 787 (Ala. Civ. App. 1984)). The Alabama Supreme Court has held that breach of implied warranty of merchantability and AEMLD claims merge when the product is "fit for the ordinary purpose for which such goods are used" but the plaintiff nonetheless alleges that the product is unreasonably dangerous. Shell v. Union Oil Co., 489 So. 2d 569, 571-72 (Ala. 1986) ("The implied warranty mandated by this section of the U.C.C. is one of commercial fitness and suitability, and a private right of action is afforded only where the user or consumer is injured by the breach of that warranty. That is to say, the U.C.C. does not impose upon the seller the broader obligation to warrant against health hazards inherent in the use of that product when the warranty of commercial fitness has been complied with.") (emphasis included); see also Bodie, 236 F. App'x at 523 ("[C]ourts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims, where the product is fit for its intended use and there is no evidence of 'non-merchantability' other than a general allegation that the product contains inherent dangers.").

That is not to say, however, that goods unfit "for the ordinary purpose for which such goods are used" cannot be unmerchantable under the U.C.C. Spain v. Brown & Williamson Tobacco Corp., 872 So. 2d 101, 108 (Ala. 2003) (distinguishing Shell on the basis that the product at issue there performed as intended and therefore was "fit for the ordinary purposes for which such goods

[12] See also § 7-2-314, cmt. 13 ("In an action based on breach of warranty, it is of course necessary to show not only the existence of the warranty but the fact that the warranty was broken and that the breach of the warranty was the proximate cause of the loss sustained."). It is well established under Alabama law that proximate causation is generally a jury question. Lands v. Ward, 349 So. 3d 219, 228 (Ala. 2021). "It is only when the facts are such that reasonable men must draw the same conclusion that the question of proximate cause is one for the courts." Id.

are used"[13]); Garrison, 322 F. Supp. 3d at 1234 ("[W]hen the evidence shows that the product is so unreasonably dangerous that it is not fit for its intended use, i.e., it is not a merchantable product, both AEMLD and warranty claims remain viable."). In addition, regardless of a showing of the product's danger, the Alabama Supreme Court has found distinct violations of the implied warranty of merchantability when the plaintiff could not use the product as intended. Garrison, 322 F. Supp. 3d at 1235 (citing Ex parte Gen. Motors Corp., 769 So. 2d at 905-06, 913-14 (Ala. 1999) and Volkswagen of Am., Inc. v. Dillard, 579 So. 2d 1301, 1302-03, 1307 (Ala. 1991)).

Plaintiff submits that her implied warranty claim in Count Five falls into this latter category – that is, a distinct violation of the of the implied warranty of merchantability when the product cannot be used as intended, regardless of a showing of "danger." (Doc. 60 at 12) (citing Garrison, 322 F. Supp. 3d at 1235). Plaintiff argues, "Like the cars that repeatedly stalled during use or that failed to accelerate, Ms. Ahmed's hip replacement did not work within weeks of being implanted. A device that could last a lifetime malfunctioned almost immediately. Based on this evidence alone, a jury could find it was not fit for its intended use."[14] (Doc. 60 at 12). Even without drawing all justifiable inferences in her favor, as the Court must do, Tipton, 965 F.2d at 998-99, Plaintiff at the least creates a "genuine dispute" via the evidentiary material in support of her Response, (see Doc. 63), as to whether the Hip Implant was "suitable or fit for the ordinary purpose for which [the

[13] The Court respectfully understands the statement in Baker v. Fiat Chrysler Autos. US LLC that "[t]he AEMLD subsumes state-law breach of warranty claims" to be overly broad. No. 1:22-CV-980, 2024 WL 85864, at *6 (N.D. Ala. Jan. 8, 2024) (citing Yarbrough v. Sears, Roebeck & Co., 628 So. 2d 478, 483 (Ala. 1993)). Spain distinguished both Shell and Yarbrough for resting on the plaintiffs' lack of evidence over the products' unfitness "for the ordinary purposes for which such goods are used." See Spain, 872 So. 2d at 106-11. "[A] claim alleging breach of implied warranty of merchantability is separate and distinct from an AEMLD claim and is viable to redress an injury caused by an unreasonably dangerous product." Id. at 111.

[14] Morris v. AngioDynamics, Inc., No. 1:23-CV-294, 2024 WL 476884 (M.D. Ala. Feb. 7, 2024), is consequently incomparable. In Morris, the Court reasoned that the implant, despite causing other harms, did not fail to achieve its intended function and therefore was not unmerchantable under the UCC. Id. at *4-5 ("The fact that these alleged harmful consequences required the removal of the device, which incidentally prevented his doctors from administering chemotherapy through the device, does not mean the device is not fit for its intended use."). Here, the Court concurs with Plaintiff that "it can be established that the device's near-immediate failure in a known, expected environment (the Plaintiff's hip joint) indicates it was not fit for its intended, ordinary use." (Doc. 60 at 12).

Hip Implant] is used." See 2 Ala. Pattern Jury Instr. Civ. 32.21 (3d ed.). Accordingly, Defendants' Motion for Summary Judgment, (Doc. 55), is **DENIED** as to Plaintiff's Count Five (Breach of Implied Warranty).

DONE and **ORDERED** this 20th day of February 2024.

s / Kristi K. DuBose
KRISTI K. DuBOSE
UNITED STATES DISTRICT JUDGE